

Notice of Allowability**Application No.**

10/520,084

Applicant(s)

LALVANI ET AL.

Examiner

Jennifer E. Graser

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to interview 3/26/09.
2. ☒ The allowed claim(s) is/are 106-110 and 116.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date ____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 3/26/09
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____.

/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gary Tanigawa on March 26, 2009.

The application has been amended as follows:

Claims 106 -110 and new claim 116 are allowed.

Claim amendments

IN THE CLAIMS

Please cancel claims 111-115 as indicated below.

This listing of claims replaces all prior versions, and listings, in this application.

106. (currently amended) A method of diagnosing in an individual a recent exposure to *M. tuberculosis*, said method comprising:

- (a) providing a T cell-containing sample from said individual;
- (b) contacting different aliquots of said sample separately with antigen compositions comprising either whole ESAT-6, or peptide epitopes derived from ESAT-6 that are 8 to 29 amino acids in length, in [[an]] ELISPOT assays in order to determine the frequency of antigen-responsive T cells which have been induced to secrete a cytokine; and
- (c) evaluating the responsive T cells in each separate ELISPOT assay, wherein a positive response using whole ESAT-6 and a negative response using said peptide epitopes indicates that the individual has recently been exposed to *M. tuberculosis*.

107. (currently amended) A method according to claim 106, wherein said peptide epitopes are 12 [[8]] to 25 [[29]] amino acids in length.

108. (previously presented) A method according to claim 106, wherein a pool of at least four different peptide epitopes is employed.

109. (currently amended) A method according to claim [[107]] 106, wherein said peptide epitopes represent all possible peptide epitopes derived from ESAT-6.

110. (previously presented) A method according to claim 106, wherein antigen presenting cells are present in said sample.

Claims 111-115 (canceled)

116. (new) A method according to claim 106, wherein said peptide epitopes are selected from the group consisting of:

MTEQQWNFAGIEAAA	(SEQ ID NO: 1),
WNFAGIEAAASAIQG	(SEQ ID NO: 2),
IEAAASAIQGNVTSI	(SEQ ID NO: 3),
SAIQGNVTSIHSLLD	(SEQ ID NO: 4),
NVTSIHSLLDGKQS	(SEQ ID NO: 5),
HSLLDGKQSLTKLA	(SEQ ID NO: 6),
EGKQSLTKLAAWGG	(SEQ ID NO: 7),
LTKLAAWGGSGSEA	(SEQ ID NO: 8),
AAWGGSGSEAYQGVQ	(SEQ ID NO: 9),
SGSEAYQGVQKQWDA	(SEQ ID. NO: 10),
YQGVQKQWDATATEL	(SEQ ID NO: 11),
QKWDATATELNNALQ	(SEQ ID NO: 12),
TATELNNALQNLART	(SEQ ID NO: 13),
NNALQNLARTISEAG	(SEQ ID NO: 14),
NLARTISEAGQAMAS	(SEQ ID NO: 15),

ISEAGQAMASTE GNV (SEQ ID NO: 16), and
QAMASTE GNV TGMFA (SEQ ID NO: 17).

2. The following is an examiner's statement of reasons for allowance:

The amendments made in claims 109 and 111 (which was replaced with new claim 116) were made to (i) correct a dependency issue (claim 109) and to (ii) delete extraneous periods in SEQ ID Nos (claim 111/116). Rejoinder of the kit claims was requested. However, no rejoinder was possible because method claims were elected in response to the restriction requirement. Claim 106 was amended to distinguish the size of the epitopes and avoid reading on the larger protein. Support for the amendment of claim 107 is found at page 8, line 10, of the specification.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1645

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

3/26/09